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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,861	12/26/2001	Hai Xing Chen	99,003.1	4882
7:	7590 05/17/2006		EXAMINER	
CUSPA Technology Law Associates			CHUNDURU, SURYAPRABHA	
11820 SW 107 Ave. Miami, FL 33176			ART UNIT	PAPER NUMBER
,			1637	
			DATE MAILED: 05/17/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/035,861	CHEN, HAI XING				
Office Action Summary	Examiner	Art Unit				
	Suryaprabha Chunduru	1637				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
<ul> <li>1) ⊠ Responsive to communication(s) filed on 03 March 2006.</li> <li>2a) ☐ This action is FINAL.</li> <li>2b) ☒ This action is non-final.</li> <li>3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.</li> </ul>						
Disposition of Claims						
4) Claim(s) 1-25 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-25 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:					

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### **DETAILED ACTION**

1. Applicants' response to the office action filed on March 3, 2006 has been entered.

## Status of the Application

2. Claims 1-25 are pending and claims 26-29 are cancelled. All amendments and arguments have been thoroughly reviewed and deemed persuasive for the reasons that follow. This action is made Non-final.

#### **New Grounds of Rejections**

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- A. Claims 1-4, 6-16, 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (USPN. 5,804,384) in view of Beattie et al. (USPN. 5, 175,209).

Muller et al. teach a method of claims 1, 7, 14, 18, 24, for sequentially detecting multiple test materials in a test sample comprising (a) adding a test sample in to a test column linear array capillary column with multiple target binding sequences) having a plurality of snares (stacked regions), said snares having multiple capture materials (different binding elements to capture analyte targets) each separated by an inert spacer (see col. 10, line 19-37, col.7, line 19-61, col. 8, line 6-67, col. 18, line 35-51),

(c) adding a labeled probe (detector probe) that specifically binds to the said first test material (see col. col. 7, line 19-61, col. 8, line 6-55, col. 18, line 35-51);

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(d) washing said test column to remove unbound probes (see 8, line 45-55, col. 18, line 43-48);

- (e) detecting the signals generated by said label and determining the presence of the first test material (see col. 9, line 5-63, col. 18, line 46-51);
- (f) adding a second labeled probe to attach to a second test material and (g and h) washing and detecting signals generated signals generated by remaining probes and detecting multiple test materials (see 8, line 29-50, indicating repeating the steps (b to e) repeatedly to obtain the signals of multiple targets of an analyte col. 10, line 21-37).

With regard to claims 1-2, 4, 7-9, Muller et al. teach multiple labels with triggering solution (see col. 11, line 21-30);

With regard to claims 3, 16, 25, Muller et al. also teach said labels are chemiluminescence labels (see col. 1, line 21-30);

With regard to claim 6, 15, 25, Muller et al. teach that the test material comprises DNA (see col. 9, line 65-67, col. 10, line 48-52);

With regard to claims 10-13, 19-23, Muller et al. also teach said method comprises positive and negative controls (see col. 8, line 22-28).

However Muller et al. did not teach plurality of snares spaced apart along a longitudinal axis of said test column separated one from another by an intervening air space

Beattie et al. teach a method for detecting multiple analytes in a sample using segmented stacked wafers in a column, each wafer is separated by intervening air spaces to allow flow through device (see col. 6, line 32-51, col. 7, line 41-66).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting multiple target nucleic acids as taught by Muller et al. with the step of including an intervening air space between snares as taught by Beattie et al. to achieve expected benefit of developing a sensitive and automated method for simultaneously detecting multiple target sequences in a sample by using less reagents and cost-effective flow through system because Beattie et al. explicitly taught t the use of a column containing stacked wafers with flow through air space permits reduced cost and use of reagents in analyzing multiple targets at a time (see col. 7, line 41-66). An ordinary practitioner would have been motivated to modify the method of detecting multiple target nucleic acids in a sample as taught by Muller et al. by incorporating the flow through air spaces between the snares (wafers) as taught by Beattie et al. to develop a sensitive and rapid cost-effective method that utilizes small volumes of sample and reagents and such modification of the method is considered obvious in the absence of secondary considerations.

B. Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (USPN. 5,804,384) in view of Beattie et al. (US 5,175,209) as applied to claims 1-4, 6-16, 18-25 above, and further in view of Lee et al. (US 5,672,475).

Muller et al. In view of Beattie et al. teach a method for sequentially detecting multiple test materials as discussed above in section 3A.

However neither Muller et al. nor Beattie et al. teach acridinium dye as a chemical label. Lee et al. teach chemical labels such as acridinium dyes (see col. 8, line 48-58).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting multiple target nucleic acids using chemical labels

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as taught by Muller et al. in view of Beattie et al. with the step of adding chemical labels as acridinium dyes as taught by Lee et al. to achieve expected benefit of developing a sensitive and improved method for detecting multiple target sequences in a sample because Lee et al. taught that the use of acridinium dyes provide stable conjugates with binding partners, does not require any catalyst to activate and can be used in sequential method processes (see col. 3, line 37-45 col. 7, line 62-67, col. 8, line 1-3, line 53-58, col. 9, line 43-46). An ordinary practitioner would have been motivated to modify the method of detecting multiple targets as taught by Muller et al. In view of Beattie et al. by incorporating the acridinium dye as taught by Lee et al. to develop a sensitive method for the purpose of obtaining stable conjugates that would be used in sequential method processes without reduction in the light emission and such modification of the method is considered obvious in the absence of secondary considerations.

#### Response to arguments:

- 4. With regard to the rejection of claims 1-4, 6-16 and 18-25 under 35 USC 103(a) as being unpatentable over Drmanac et al. in view of Muller et al., Applicants arguments are found persuasive and the rejection is withdrawn herein and new grounds of rejections directed to address the arguments regarding snares spaced apart along a longitudinal axis separated by one another by an intervening air space.
- 5. With regard to the rejection of claims 1-4, 6-16 and 18-25 under 35 USC 103(a) as being unpatentable over Drmanac et al. in view of Muller et al. further in view of in view of Patel et al., Applicants arguments are found persuasive and the rejection is withdrawn herein and new grounds of rejections

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### Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday,

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru Patent Examiner Art Unit 1637